

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDTECH PRODUCTS INC.,)
90 North Broadway)
Irvington, New York 10533)
Plaintiff,)
v.) Civil Action No. 07 CV 3305 (SCR)
POWER PRODUCTS, INC.)
d/b/a SPLINTEK,)
3325 Wyoming Street)
Kansas City, Missouri 64111)
Defendant.)

)

DECLARATION OF JEAN BOYKO

I, Jean Boyko, pursuant to 28 U.S.C. § 1746, declare and say as follows:

1. My name is Jean Boyko. I am Senior Vice-President of Quality and Regulatory Affairs for Prestige Brands Holdings, Inc., the parent corporation of Medtech Products Inc. ("Medtech"). I am over the age of 18 and have personal knowledge of the facts and circumstances discussed herein. I submit this declaration in support of Medtech's Motion for Preliminary Injunction.

2. On March 3, 2006, Medtech became the first company to obtain formal FDA approval to market an over-the-counter ("OTC") dental protective device for night time tooth grinding or bruxism. A true and correct copy of the FDA approval is attached hereto as Exhibit 1.

3. Sales of the NIGHTGUARD™ dental protective device that were made before March 3, 2006 were made OTC with the knowledge of the FDA but without formal approval.

4. Power Products received a Section 510(k) premarket authorization from the FDA for dental protectors that are for prescription use only, and for patients 18 years of age or older. A true and correct copy of the Power Products premarket authorization is attached hereto as Exhibit 2.

5. The Power Products device is an adjustable, pre-formed oral appliance that includes two bite pads. The Power Products product is not a full-occlusion mouthpiece.

6. The FDA has determined that non-fully occlusive nighttime protective devices involve an unacceptable risk of super eruption (if not prescribed and overseen by a dentist), and the FDA's Dental Advisory Panel has issued an independent recommendation, after a full public hearing and public vote, that only full occlusion mouthpieces should be permitted to be sold OTC.

7. Medtech caused two letters to be sent to the FDA on October 20 and November 22, 2006 concerning Power Products' OTC sales of its dental protector device. True and correct copies of the letters to the FDA are attached hereto as Exhibits 3 and 4.

8. The FDA issued a "WARNING LETTER" to Power Products dated January 16, 2007. A true and correct copy of the warning letter is attached hereto as Exhibit 5.

9. On March 8, 2007, in a meeting with myself and other representatives of Medtech on related matters, the FDA reaffirmed its position on the inappropriateness of non-fully occlusive dental protector devices for OTC use.

I DECLARE UNDER THE PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

DATED THIS 23 DAY OF MAY, 2007.



JEAN BOYKO